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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

26474 7590 09/27/2010

NOVAK DRUCE DELUCA + QUIGG LLP
300 NEW JERSEY AVENUE NW
FIFTH FLOOR
WASHINGTON, DC 20001

EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/27/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GUNTHER BERNDL, JORG BREITENBACH,
FOLKER RUCHATZ, AXEL SANNER, and HEINRICH SACK

Appeal 2009-015182
Application 09/937,313
Technology Center 1600

Before ERIC GRIMES, MICHAEL P. COLAIANNI, and
BEVERLY A. FRANKLIN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a process for producing a pharmaceutical excipient. The Examiner has rejected the

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 10-12, 14-18, and 20-24 are on appeal. Claims 10 and 22 are the only independent claims and read as follows:

10. A process for producing an excipient adapted for use in a solid pharmaceutical dosage form, wherein said excipient is in the form of a free-flowing powder and consists essentially of:

a pharmaceutically acceptable polymer, wherein the polymer is a homo- or copolymer of N-vinylpyrrolidone, which is a water-soluble polymer with Fikentscher K values of from 12 to 100, and

from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance, comprising ethoxylated sorbitan fatty acid esters, or the products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid,

said process comprising either:

spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or

processing the polymer and the surface-active substance in an extruder to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder.

22. A process for producing a free-flowing powder excipient for use in a solid pharmaceutical dosage form consisting essentially of:

a pharmaceutically acceptable polymer, and from 10 to 50% by weight, based on the total weight of the excipient, of a liquid or semisolid solubilizing surface-active substance, wherein the pharmaceutically acceptable polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone, and is a water-soluble polymer with Fikentscher K values of from 12 to 100

the process comprising producing the free-flowing powder excipient by one of:

spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or

extruding the polymer and the surface-active substance to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder, wherein

the surface active substance is in a suitable concentration to keep the excipient free flowing.

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

- Claims 10-12, 14-18, 20, and 22-24 Guzi,[2] Staniforth,[3] and Zeligs;[4]
- Claims 10, 15, 16, 18, 20, and 21 in view of Kolter,[5] Staniforth, and Zeligs.

I.

Issue

The Examiner has rejected claims 10-12, 14-18, 20, and 22-24 under 35 U.S.C. § 103(a) as being obvious in view of Guzi, Staniforth, and Zeligs.

The Examiner finds that Guzi discloses "a method of making an excipient comprising spray-drying a solution comprising 15-40 % by weight of a nonionic dispersing agent, and a polymer such as N-vinylpyrrolidone" (Answer 3) and concludes that it would have been obvious to substitute the surfactant taught by Staniforth or Zeligs in the Guzi composition to improve the compressibility or stability of the spray dried particles (*id.* at 5).

Appellants contend that the cited references would not suggest the claimed invention because substituting the surfactant of Staniforth or Zeligs for the surfactant of Guzi would not result in an excipient that is suitable for

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[2] Guzi, Jr. et al., US 4,127,422, issued Nov. 28, 1978.
[3] Staniforth et al., US 5,858,412, issued Jan. 12, 1999.
[4] Zeligs et al., US 6,086,915, issued July 11, 2000.
[5] Kolter et al., US 6,066,334, issued May 23, 2000.

use in a solid pharmaceutical dosage form, as required by claims 10 and 22 (Appeal Br. 9).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the cited references would have made obvious the claimed methods of making an excipient suitable for use in a solid pharmaceutical dosage form?

Findings of Fact

1. Guzi discloses a method of making

> a dry water-dispersible pigment composition … comprising the steps of: forming a homogeneous mixture comprising milled or homogenized pigment, water and, by weight of the pigment, (a) from 15 to 45% of a nonionic dispersing agent … (b) from 10 to about 67% of at least one water-dispersible nonionic polymer selected from the group consisting of (1) an at least partially hydrolyzed polymer of vinyl acetate and (2) a polymer of an N-vinyl pyrrolidone and (c) from 0 to about 40% of a nonionic colloid; and removing the water from said mixture until a dry composition is obtained.

(Guzi, col. 2, ll. 26-43.)

2. Guzi discloses that its compositions "hav[e] broad compatibility in latex and other aqueous systems, such as paper coating compositions, disposable nonwovens, melamine-formaldehyde laminates, ink systems and universal colorant systems" (*id.* at col. 1, ll. 61-64).

3. Guzi discloses that

> [t]ypical pigments include organic pigments such as diarylide yellow, the phthalocyanine blues and greens, the quinacridone reds and violets, dioxazine violet and the like; and inorganic pigments such as the cadmium reds and yellows, the cadmium sulfide type pigments, the molybdate oranges, iron oxide yellow and red, and the like. Also suitable are the hydrophilic

> type pigments such as, for example, titanium dioxide and the lead chromate colors.

(*Id.* at col. 2, l. 62 to col. 3, l. 2.)

4. All of Guzi's working examples describe tinting commercial latex paint formulations with its dry pigment compositions (*id.* at col. 5, l. 54 to col. 10, l. 6).

Principles of Law

> If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim. . . . If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999).

Analysis

Claim 10 is directed to a "process for producing an excipient adapted for use in a solid pharmaceutical dosage form," by either spray-drying or extruding a defined composition. Claim 22 is similarly directed to a "process for producing a free-flowing powder excipient for use in a solid pharmaceutical dosage form," by either spray-drying or extruding a defined composition.

Appellants argue that substituting the surfactant of Staniforth or Zeligs for the surfactant of Guzi, as suggested by the Examiner, would not result in an excipient that would be suitable for use in a solid pharmaceutical dosage form (Appeal Br. 9). Appellants further argue that "a skilled artisan had no apparent reason to assume that the pigments employed in the Guzi pigment compositions - intended primarily for use in commercial latex paints - would be suitable for use in a solid pharmaceutical dosage form" (*id.*).

The Examiner responds that the preambles of claims 10 and 22 are "merely a future intended use limitation," not claim limitations (Answer 10). The Examiner further responds that the "ingredients are all generally recognized as safe and are used in pharmaceutical dosage forms as seen in the Staniforth and Zeligs patents" (*id.*).

Appellants' arguments are persuasive. The preamble of a claim limits the scope of the claim when it recites limitations or provides meaning necessary to the body of the claim. *Pitney Bowes*, 182 F.3d at 1305. Here, the preambles of claims 10 and 22 state that the claimed process produces an excipient that is suitable for use in a solid pharmaceutical dosage form. We agree with Appellants that the preamble language limits the claimed processes to those producing compositions suitable for pharmaceutical use.

The Examiner's rejection relies on the substitution of the surfactants of Staniforth and Zeligs into the process of Guzi. However, Guzi is directed to the preparation of pigment compositions for use in paints and other non-pharmaceutical compositions. The Examiner has not adequately shown that the product of the Guzi process would be suitable for use in a

pharmaceutical dosage form. The Examiner asserts that all of the ingredients are generally recognized as safe but has not pointed to any evidence to establish that the pigments used in Guzi's process would be suitable for use in pharmaceutical compositions.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the cited references would have made obvious the claimed methods of making an excipient suitable for use in a solid pharmaceutical dosage form. The rejection of claims 10-12, 14-18, 20, and 22-24 as being obvious in view of Guzi, Staniforth, and Zeligs is reversed.

II.

Issue

The Examiner has rejected claims 10, 15, 16, 18, 20 and 21 under 35 U.S.C. § 103(a) as being obvious in view of Kolter, Staniforth, and Zeligs. The Examiner finds that Kolter discloses a spray-dried "redispersible microparticle formulation comprising polyvinylpyrrolidone and up to 10% of a surfactant" (Answer 6). The Examiner concludes that "[r]egarding the specific surfactant/emulsifiers, … it would have been well within the level of skill in the art to simply substitute the emulsifiers/dispersing agents" of Staniforth and Zeligs into the Kolter process (*id.* at 7).

Appellants contend that the references do not suggest the claimed process because Kolter spray-dries a dispersion and does not disclose or suggest spray-drying a solution, as required by the claims (Appeal Br. 11).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the cited references disclose or suggest "spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer?"

Additional Findings of Fact

5. Kolter discloses "redispersible polymer powders or polymer granules consisting of polyvinyl acetate and N-vinylpyrrolidone-containing polymers as binders for producing solid pharmaceutical presentations" (Kolter, col. 1, ll. 6-9).

6. Kolter discloses that "[p]olyvinylpyrrolidone has excellent solubility in water" while "[p]olyvinyl acetate is insoluble in water and has not to date been described as binder" (*id.* at col. 2, ll. 48-53).

7. Kolter discloses that the "redispersible polymer powders are produced by initial emulsion polymerization of vinyl acetate, then addition of the N-vinylpyrrolidone-containing polymer …, to the resulting shear-stable and fine-particle dispersion, and spray-drying of the mixture" (*id.* at col. 2, ll. 63-67).

Analysis

Claim 10 specifies the process step of "either: spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or processing the polymer and the surface-active substance in an extruder to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder."

The Examiner does not find that the cited references disclose processing by extrusion, but relies on Kolter as disclosing the process step of spray-drying a solution containing the polymer and the surface active substance.

Appellants contend that "Kolter describes spray drying a fine-particle dispersion not a solution" (Appeal Br. 11) and that Kolter explains that "polyvinyl acetate is insoluble in water" (*id.*).

The Examiner responds that "emulsifiers are added to the mixture creating a homogeneous [ ] mixture of liquids…. This homogeneous mixture of liquids would effectively function identically to the instant claims." (Answer 10.)

Appellants' arguments are persuasive. Although the Examiner reasons that Kolter's mixture would therefore "effectively function identically to the instant claims" (Answer 10), the claims require spray-drying a *solution* not a dispersion, even if the dispersion may be homogeneous. The Examiner therefore has not shown that the cited prior art discloses or suggests all of the claim limitations.

The rejection of claims 10, 15, 16, 18, 20 and 21, as obvious in view of Kolter, Staniforth, and Zeligs is reversed.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the cited references disclose or suggest "spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer."

SUMMARY

We reverse the rejection of claims 10-12, 14-18, 20, and 22-24 as obvious based on Guzi, Staniforth, and Zeligs, and the rejection of claims 10, 15, 16, 18, 20, and 21 as obvious based on Kolter, Staniforth, and Zeligs.

REVERSED

cdc

NOVAK DRUCE DELUCA + QUIGG LLP
300 NEW JERSEY AVENUE NW
FIFTH FLOOR
WASHINGTON, DC 20001